



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
Office of Patent Legal Administration

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AUG 02 2010

In re Patent Term Extension Application of	:
United States Department of Agriculture for	:
U.S. Patent No. 5,135,759	:
Issue Date: August 4, 1992	:
Application No. 07/692,958	:
Filing Date: April 26, 1991	:
Title: Method To Preselect the Sex of	:
Offspring	:

The request for withdrawal of interim extension of patent term, filed January 29, 2010, the petition under 37 C.F.R. § 1.183 and 1.182 filed on July 27, 2010 and the request for subsequent interim patent term extension pursuant to § 156(d)(5)(C), filed on July 27, 2010, have been forwarded to the Office of the Associate Commissioner for Patent Examination Policy in the United States Patent and Trademark Office (the "USPTO") for consideration.

Because the USPTO properly granted the interim extension of July 28, 2009, based on the August 4, 2009 expiration date of US. Patent No. 5,135,759, the request to withdraw the interim extension is **DENIED**. Because §§ 1.182 and 1.183 do not provide the USPTO with authority to grant an extension of time to comply with a statutory time period (i.e., waive a statutory requirement), the petition is **DENIED**. Additionally, because the request for second interim patent term extension fails to comply with the timeliness requirement of § 156(d)(5)(C), the request for a second interim extension is **DENIED**.

Factual Background

1. On August 4, 1992, the USPTO granted U.S. Patent No. 5,135,759 (the '759 patent) to Lawrence A. Johnson who assigned his rights to the United States Department of Agriculture ("USDA").
2. On June 8, 2009, the USDA filed a request for interim patent term extension under the provisions of 35 U.S.C. § 156(d)(5). Because the patent was set to expire on August 4, 2009, the application on June 8, 2009 was timely filed within the period beginning 6 months and ending 15 days before the original expiration date of the patent as required by § 156(d)(5)(A).
3. On July 28, 2009, the USPTO granted an interim patent term extension pursuant to § 156(d)(5)(B) for the period of one year from the original expiration date of August 4, 2009,

through and including August 4, 2010. On August 4, 2009, notice of the grant of interim extension was published in the Federal Register in accordance with § 156(d)(5)(B).

4. On January 29, 2010, USDA filed a request to withdraw the interim extension granted on July 28, 2009 on the theory that the actual expiration date of the '759 patent was April 26, 2011 based on the change to § 154 under the Uruguay Round of Agreements Act ("URAA").

5. On July 27, 2010, USDA ("USDA" or "Petitioner") filed a petition under 37 C.F.R. §§ 1.182 and 1.183 ("Petition") along with a request for a second subsequent interim patent term extension pursuant to § 156(d)(5)(C). Petitioner alleges that it filed its second interim extension request late due to a shortcoming of an automated docketing system used by a law firm that represents Petitioner's licensee.

Decision

A. USPTO's previously granted interim extension was proper based on the August 4, 2009 expiration date.

Section 156(d)(5) sets forth certain criteria which must be met in order for the USPTO to grant an interim extension. First, the regulatory review period for the product claimed by the patent must be in the "approval phase," that is, "the period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) of § 156" must have begun for the product. See § 156(d)(5)(A). USDA met this requirement because their Premarket Approval application ("PMA") is undergoing continuing review at FDA. Second, an application must be submitted during the period beginning 6 months, and ending 15 days before such term [of the patent] is due to expire. See § 156(d)(5)(A). USDA met this requirement by submitting their application on June 8, 2009, clearly within 6 months prior to the August 4, 2009 expiration date and not less than 15 days before the August 4, 2009 expiration date. Section 156(d)(5)(A)(i)-(v) sets forth the information that the application for extension must contain. USDA's application fulfilled these statutory requirements. Under § 156(d)(5)(B), when the Director determines that the patent would be eligible for an extension of patent term under § 156, except for the permission for commercial marketing or use, the Director shall publish in the Federal register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year. Here, the USPTO accepted the timely application for interim extension filed by USDA on June 8, 2009, then USPTO fulfilled its statutory mandate set forth in § 156(d)(5)(B) and granted an interim extension for the '759 patent and provided notice of the interim extension grant by way of the Federal Register publication on August 4, 2009.

On January 29, 2010, USDA filed a request seeking withdrawal of the previously granted interim extension. The rationale for the request was that the '759 patent does not expire until April 26, 2011. According to the January 2010 request, the '759 patent, which was in force on June 8, 1995 (the effective date of the URAA), receives a patent term which is the greater of 17 years from grant or 20 years from the filing date of the application. Petitioner is correct regarding the ability of the '759 to acquire the longer of the two terms, but petitioner is incorrect

in its approach to calculating the 20-year term involved here, and hence its conclusion that the 20-year term is longer than the conventional 17-year term is also flawed.

Although USDA is correct that the actual filing date of the application which matured into the '759 patent was April 26, 1991, the trigger date for the twenty-year term for the '759 patent is actually May 10, 1989 (based on a benefit claim, under 35 U.S.C. § 120, in the '759 patent to an earlier application filed May 10, 1989). See 35 U.S.C. § 154(a)(2) (defining the start date of the 20-year term as the earliest application filing date to which the issued patent claims priority under 35 U.S.C. §§ 120, 121, or 365(c)). Thus, the expiration date of the '759 patent, which would be calculated as the greater of 17 years from grant (August 4, 2009) or 20 years from the earliest claimed filing date (May 10, 2009), was August 4, 2009. See 35 U.S.C. § 154(c) (providing that the term of a patent in force when the URAA was enacted is the longer of 17 years from grant or the expiration of the 20-year term provided in 35 U.S.C. § 154 (a)(2)).

Because the interim extension was properly granted, the USPTO will not withdraw the previously granted interim extension. Therefore, the request is denied. As a result, the expiration date of the '759 patent's initial interim extension is August 4, 2010.

B. 37 C.F.R. §§ 1.182 and 1.183 do not permit the USPTO to extend the time period to file an application for a subsequent interim patent term extension.

Because Petitioner's request for a second interim extension was not filed 30 days before the expiration of initial interim extension, Petitioner relies on the provisions of 37 C.F.R. §§ 1.182 and 1.183 to extend the time period within which to file a subsequent interim patent term extension application. Petition at 1. Both of these regulations relate to mechanisms for individuals to file petitions to seek waiver of a rule or relief from the enforcement of a rule.

In particular, 37 C.F.R. 1.182 addresses cases where there is no other specific rule which provides a mechanism for a petitioner to seek redress of a situation. Here, petitioner appears to be seeking a general extension of time within which to file a subsequent interim patent term extension application in accordance with 35 U.S.C. § 156(d)(5)(C) and 37 C.F.R. § 1.790(a). Although the USPTO has authority to grant relief over certain regulatory requirements, the USPTO has no authority to grant relief for failure to comply with a statutory requirement. Because the relief that petitioner seeks is from a statute, the USPTO, without any statutory authority to grant such relief, cannot excuse failure to comply with the statutory timing requirement of § 156(d)(5)(C), and thus, must deny the petition under 37 C.F.R. § 1.182.

Similarly, 37 C.F.R. § 1.183 addresses cases where, under extraordinary circumstances, waiver of a rule is necessary when justice would so require. Although petitioner alleges an extraordinary circumstance, that is, the failure of their computer docketing system to track the proper (or any) due date for a subsequent interim patent term extension application, waiver of a regulatory requirement would not provide sufficient relief such that the USPTO could accept the late filed subsequent interim patent term extension application. Petitioner's situation is controlled by statute, thus, there is no rule which can be waived which would provide sufficient relief. Accordingly, the USPTO must deny the petition under 37 C.F.R. § 1.183.

C. The plain meaning of 35 U.S.C. § 156(d)(5)(C) mandates that grant of a subsequent interim patent term extension is predicated on a timely filed subsequent application for interim extension.

Petitioner argues that the language, structure and purpose of § 156 give the USPTO discretion to authorize a second interim patent term extension outside the statutory timing window. Petition at 5. Petitioner argues that the meaning of “shall” in § 156(d)(5)(C) does not always mean a mandatory, nondiscretionary duty and should be interpreted by examining the language and purpose of the statute. Petition at 5.

The USPTO finds that the best definition of “shall” as used throughout section 156 indicates an imperative duty based upon the text, structure, and purpose of the statute. In making this determination, the USPTO notes that section 156(d) squarely deals with the procedural requirements for obtaining a patent term extension. In particular, section 156(d)(5)(C) is solely directed to the proper time period for submitting an application for a subsequent interim patent term extension. The USPTO’s interpretation here is thus undertaken in the course of governing the conduct of its proceedings.

Any analysis of a statute begins with the language of the statute itself. The statutory provision at issue here reads:

[t]he owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph Each such subsequent application *shall* be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

35 U.S.C. § 156(d)(5)(C) (emphasis added). To determine what the term “shall” means, the USPTO looks to the words surrounding that term, namely the phrase, “[e]ach subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.” The statutory provision requires that an application be made. “A subsequent application shall be made” is interpreted to mean that the patent owner or his agent must submit an application to the USPTO. Because the USPTO can only act upon documents filed with the USPTO, the statute clearly requires a submission. If the timing requirement of § 156(d)(5)(C) were discretionary or non-essential as Petitioner argues, Congress could have ended the requirement and simply require an application be made. However, in enacting the provision Congress contemplated that the submission would be made to USPTO prior to expiration of the previously granted interim extension. In particular, Congress required a specific time period—during the period beginning 60 days before, and ending 30 days before the expiration of the previously granted interim extension—for submission of the application. By including a time period within which to file the subsequent interim patent term extension application, Congress sought to ensure timely consideration of the subsequent interim patent term extension application by the USPTO which, if the other statutory criteria were met, would result in issuance of a certificate of interim patent term extension. Thus, the plain meaning of “shall” in § 156(d)(5)(C) imposes an imperative duty upon any patent owner seeking additional term under § 156(d)(5).

1. The USPTO has previously interpreted the timing provision of § 156(d)(5)(C).

The provisions which were codified at 35 U.S.C. § 156(d)(5)(A)-et seq. were passed in Public Law 103-179 as part of the Patent and Trademark Office Authorization Act of 1993. Within two months of passage of the new interim patent term extension provisions, the USPTO issued guidelines regarding implementing the interim extension provisions in the Official Gazette, "Guidelines For Interim Extension Under 35 U.S.C. 156(d)(5) of a Patent Term Prior To Regulatory Approval of a Product For Commercial Marketing or Use--Public Law 103-179 (December 3, 1993)," 1159 Off. Gaz. Pat. Office 12 (February 1, 1994) (copy attached as exhibit 1). There, the USPTO explained that the conditions for interim extension of patent term required an application to be submitted:

...during the period beginning 6 months, ending 15 days, before the expiration of the patent term; or in the case of a subsequent interim extension, during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

1159 Off. Gaz. Pat. Office 12 § B.

Following the initial guidelines for interim patent term extensions under 35 U.S.C. § 156(d)(5) of February of 1994, in accordance with 35 U.S.C. § 2(a)(2)(A), the USPTO engaged in notice and comment rulemaking contemporaneous with the passage of the statute. There the USPTO promulgated new regulations to govern conduct before the agency with respect to applications for interim patent term extension involving patents claiming products which are under on-going regulatory review. The USPTO issued a notice of proposed rulemaking in November of 1994 providing the regulatory framework for submission of applications for interim patent term extension under 35 U.S.C. § 156(d)(5). See 59 Fed. Reg. 56015 (November 10, 1994). After receiving a single comment relating to the scope of a proper applicant for patent term extension, the USPTO issued the final rules which implement the provisions of Public Law 103-179 relating to interim patent term extension. See 60 Fed Reg. 25616 (May 12, 1995). Additionally, the USPTO, in providing further guidance on the implementation of the Hatch-Waxman Act in the Manual of Patent Examining Procedure ("MPEP") explain at MPEP 2755, that "a series of one-year interim extension may be granted if requested in a timely manner (in the window of time between thirty and sixty days before the extended expiration date)." In issuing contemporaneous guidelines, promulgating regulations and including guidance in the MPEP regarding the filing window for subsequent applications under 35 U.S.C. § 156(d)(5)(C), the USPTO has previously provided its statutory interpretation of the provision at issue here.

2. The USPTO has no discretion to issue a subsequent interim patent term extension under 35 U.S.C. § 156(5)(d)(C) without a timely filed subsequent interim patent term extension application.

Petitioner urges that based on their construction of "shall" in § 156(d)(5)(C), the USPTO has discretion to accept a late filed subsequent interim patent term extension application and this is an appropriate case to exercise that discretion. Petition at 10. While the USPTO appreciates the importance of the '759 patent to USDA and is aware of the impact a denial of an interim patent term extension may have on the USDA, the statutory time period is non-discretionary.

That is, § 156(d)(5) neither provides for a grace period, nor gives the USPTO discretion to extend the time period for submitting a subsequent interim patent term extension application. As such, the PTO is bound by statute to implement the provisions of § 156(d)(5)(C), including the timeliness provisions.

The USPTO must adhere to the Congressional mandate of § 156(d)(5)(C) that, “[e]ach such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.” Because USDA’s application was filed 8 days before expiration preceding interim extension (i.e., outside of the period beginning 60 days before, and ending 30 days before the expiration of the preceding interim extension), the application is untimely and must be denied.

Petitioner also indicates that should the USPTO grant the second interim extension and believe that a sanction is appropriate, the sanction could be to subtract the time of the late filing from the time of the extension granted. Petition at 10-11. There is no provision in any part of title 35 of the United States code which gives authority to the USPTO to grant an interim patent term extension for a late filed subsequent application for interim extension and certainly no authority to administer a sanction if the USPTO could extend the period within which to file a subsequent interim patent term extension application.

D. Petitioners arguments regarding statutory construction are unpersuasive

Petitioner argues that the statute “requires” the timely filing (by using “shall”) and the rule uses “may.” Petition at 6. At the outset, Petitioner’s argument fails to appreciate the “if” at the end of the introduction to 37 C.F.R. 1.720(a). Specifically, the rule states, “[t]he term of a patent may be extended if.” The use of “if” in the rule language serves to require certain information in order for the Director to have authority to issue an extension. Thus, the “may” to which petitioner refers, when read in conjunction with the “if” of the phrase, actually means “may only.” In essence, the USPTO may only grant a patent term extension if certain conditions are met. Because the USPTO may only grant a patent term extension if certain conditions are met, the “may. . . if” of 37 C.F.R. § 1.720 has the effect of requiring a timely filing, i.e. “shall.” The USPTO’s use of “may . . . if” does not mean that the USPTO is departing from “shall.”

Petitioner points out that when Congress repeats the same word in the same statute, it intends for that word to have the same meaning. Petition at 6 (quoting *The Medicines Company v. Kappos*, ___ F.Supp. ___, 2010 WL 1005261 *5-8 (E.D. Va. March 16, 2010)). Were the USPTO to accept Petitioner’s argument that “shall” is discretionary in § 156(d)(5)(C) and apply the other tenet that Petitioner espouses, namely that the same word in the same statute should be given the same meaning, would inherently mean that when an applicant for patent term extension fulfills the statutory requirements for receiving a certificate of extension, the USPTO could, within their discretion, choose to deny the grant of a certificate of interim extension.

As an example, section 156(d)(5)(B), the statutory provision under which an initial interim extension must be filed for a patent claiming a product undergoing continuing regulatory review, uses “shall” in two different instances. The statute provides:

[i]f the Director determines that, except for permission to market or use the product commercially, the patent would be eligible for extension of the patent term under this section [§ 156], the Director

shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review and **shall** issue to the applicant a certificate of interim extension for a period of not more than 1 year.

See § 156(d)(5)(B) (emphases added). The first imperative is that the Director **shall** publish a notice of the grant of an interim extension in the Federal Register. The second imperative is that the Director **shall** issue the certificate of interim extension for a period of not less than 1 year. Applying Petitioner's rationale that "shall" is discretionary, when the patent owner has met the requirements of the statute, the USPTO could, within their discretion, choose to deny the certificate of interim extension. Clearly, such a reading would not further the letter of the law and would be contrary to the intent of the patent term restoration provisions of the Hatch-Waxman Act. Additionally, as noted by the use of "shall" the statutory scheme does not give the USPTO any latitude to not grant an extension. Thus, since "shall" indicates an imperative duty upon the USPTO to grant an extension when the statutory requirements have been met, the same recitation of "shall" can admit of no other reading than an imperative duty upon the applicant to timely submit a subsequent interim patent term extension application.

Furthermore, Petitioner's reading fails to comport with the plain meaning of the statute and the mandate articulated by the court in *Merck & Co. Inc. v Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317 (Fed. Cir. 2007). As Petitioner accurately notes from *Merck*, the Federal Circuit held that "shall be extended" indicated an imperative. Petitioner notes that other parts of § 156 "require a more flexible interpretation." Petition at 6. While the *Merck* court did note that some parts of § 156 are flexible, the "flexibility" noted by the *Merck* court was in relation to the meaning of "original expiration date" as stated in § 156(a) in light of the Uruguay Round Agreements Act when the issue of "original expiration date" was litigated in *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996). There was no suggestion by the *Merck* court in 2007 or the earlier *Merck* court in 1996 that the recitation of "shall" throughout § 156 was anything other than imperative duty.

Next Petitioner argues that the USPTO has indicated that the timing provision of § 156(d)(1) is remedial as stated in the USPTO's letter to FDA of July 12, 1988, in U.S. Patent No. 4,146,029, and as such, should be liberally construed. Petition at 6. First, the timeliness language of § 156(d)(1) and § 156(d)(5)(C) are not the same, one is in reference to a time period following the grant of permission for commercial marketing or use of the product subject to the regulatory review period and the other is in reference to days before expiration of a preceding interim extension. Second, this document is not "precedent" or a "decision," but instead is simply a letter from USPTO to FDA wherein USPTO expresses the opinion that the date of FDA approval should be excluded from the sixty-day count for purposes of § 156(d)(1)—a view USPTO has since repudiated and because it involves a different statutory provision, irrelevant to the calculus here. Third, while section 156, and more generally the Hatch-Waxman Act, in part, was certainly meant to remedy the loss of effective patent term due to lengthy regulatory delay, it does not follow that every provision within section 156 is "remedial." In section 156(d)(5)(C), Congress provided a window within which a patentee can file its subsequent interim patent term extension application. No provision for extension of the time period is included. By creating such a non-extendable period, Congress provided a date-certain by which all players would know their future rights.

Petitioner has accurately pointed out instances where the USPTO has interpreted statutory provisions in order to ensure no loss of rights to applicants and patentees. Petition at 7. In all of those instances, Congress has provided the avenue for the relief available at the agency, and thus to the applicant or patentee. In light of that, it speaks volumes that Congress provided no avenue to allow the USPTO to accept a late subsequent interim patent term extension application filed under section 156(d)(5)(C). Given Congress's unquestionable awareness that lawyers make mistakes, and the various provisions it provided to redress those mistakes, Congress's failure to include a similar provision related to the section 156(d)(5)(C) thirty to sixty day filing window compels the conclusion that Congress did not intend the provision to be remedial, or to be interpreted in a way that benefits late-filing applicants.

Petitioner argues that the USPTO has discretion because the time window set forth in § 156(d)(5)(C) is not essential to § 156. Petition at 7. Although Petitioner states that the time window is a detail of procedure, Petitioner fails to point to any statutory language or legislative history which would indicate that the timing requirement is not essential or merely a detail of procedure. When Congress used the word "shall," in section 156, contrary to the position of Petitioner, Congress intends for the action by the administrator of the statute to be an imperative duty. See *Merck & Co. v. Hi-Tech Pharmacal Co.* at 1322. Furthermore, to make the timing requirement of § 156(d)(5)(C) non-essential would mean that the public notice function of § 156(d)(5)(B) would not be served since there would be no timely publication of the notice that a patent was being extended based on the on-going regulatory review of a product claimed by the patent.

Petitioner next urges that equity weighs in favor of granting the untimely filed subsequent interim patent term extension application. However, the Federal Circuit has pointed out that interpreting the timing requirement of § 156(d)(1) is "purely a case of statutory interpretation, so any equitable considerations" are inappropriate. See *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829 (Fed. Cir. 1989). Thus, similarly, interpreting the timing requirement of § 156(d)(5)(C) would also involve pure statutory construction, and as such, any equitable consideration would not be appropriate.

Petitioner cites to *Blacklight Power Inc. v. Rogan*, 295 F.3d 1269 (Fed. Cir 2002) for the proposition that the meaning of "shall" in § 156(d)(5)(C) does not always mean a mandatory, nondiscretionary duty and should be interpreted by examining the language and purpose of the statute. Petition at 5 and 8. It is noted that the Federal Circuit's discussion of the use of "shall" in a different statutory provision, 35 U.S.C. § 151, was indeed mandatory:

[w]e agree with the PTO that while the words, "shall issue" indeed impose a duty, the preface to § 151 places a condition on that duty. This preface conditions not only the issuance of the notice of allowance, but also the ensuing steps of § 151. . . .Section 151 does not prohibit the Office from interrupting the sequence if the condition set forth in the opening clause is reasonably believed not to have been met.

Blacklight at 1273.

In *Blacklight*, the preface condition, "[i]f it appears that applicant is entitled to a patent under the law," was not met. Thus, even though the remaining "steps" of § 151 had been met, the USPTO

was within its authority when it withdrew the application from issue in order to fulfill their obligation of issuing valid patents. *Id.*

In the *Blacklight* case, the USPTO did not exercise discretion in its interpretation of “shall” in §151. Rather, because issuance of a patent is predicated on entitlement “to a patent under the law,” the USPTO recognized, albeit after payment of the issue fee, that the applicant in *Blacklight* did not appear to be entitled to a patent under the law. Thus, the USPTO adhered to their statutory mandate because, even though the issue fee was paid, the “written notice of allowance” (§ 151, ¶1) was premature in *Blacklight* since the applicant failed to comply with all of the patent laws.

In *Ute Indian Tribe v. Hodel*, 673 F.Supp. 619, 620 (D.D.C 1987), the court there held that the fiduciary duty of the Secretary as trustee overcame the “shall” language. *Ute Indian Tribe* at 622. In that case, although there was “discretion” by the Secretary to decide whether to approve per capita payments from the judgment fund, the discretion was only due to the stringent fiduciary duty as trustee, such fiduciary duty is clearly not present here. *Id.*

Petitioner urges that the court held in *The Medicines Company v. Kappos*, ____ F.Supp. 2d ____, 2010 WL 1005261, at *5-8, that the USPTO abused its discretion in denying an extension application filed outside the 60 day time period of § 156(d)(1). Petitioner’s characterization of *The Medicines Company* decision does not comport with the actual holding of the case. There the court vacated the previously issued denial and remanded the case back to the agency with instructions that the USPTO had discretion to consider a business day construction of the word “date” in § 156(d)(1) of the statute and that the USPTO must properly address every argument of the applicant for extension in their request for reconsideration. Moreover, the issue in *The Medicines Company* was whether the application for patent term extension PTE was actually timely filed based on construction of the term “date” in § 156(d)(1). The issue was not whether the PTO has discretion to accept a late filed patent term extension application in general. Specifically, any discretionary authority by the USPTO to accept a late filed application for patent term extension was not at issue. Under *The Medicines Company*’s construction, their application for patent term extension was timely based on construing the word “date” in § 156(d)(1) as business date. Here, Petitioner admits that their application for a subsequent interim patent term extension is late.

In summary, as discussed *supra*, “shall” imposes upon the USPTO an imperative duty. Accordingly, the USPTO has no authority to accept a late filed subsequent interim patent term extension application and thus cannot grant the petition for an extension of the time period in § 156(d)(5)(C) to file a subsequent interim patent term extension application.

CONCLUSION

1. The request for withdrawal of interim extension filed January 29, 2010 is **denied**. The petition filed July 27, 2010 for an extension of the timeliness requirement in § 156(d)(5)(C) for filing a subsequent interim patent term extension application is **denied**. The request for subsequent interim patent term extension is **denied**.
2. This decision is designated a **final agency action** within the meaning of 5 U.S.C. § 704.
3. Telephone inquiries related to this decision should be directed to Mary C. Till, Legal Advisor, at (571) 272-7755

Further correspondence with respect to this matter should be addressed as follows:

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Brian E. Hanlon

Director

Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

Reg. No.	Serial No.	Reg. Date
954,702	72/418,096	3/06/1973
954,708	72/399,766	3/06/1973
954,714	72/409,562	3/06/1973
954,715	72/391,295	3/06/1973
954,716	72/397,761	3/06/1973
954,718	72/406,791	3/06/1973
954,721	72/408,453	3/06/1973
954,722	72/373,829	3/06/1973
954,727	72/378,860	3/06/1973
954,733	72/368,280	3/06/1973
954,735	72/380,477	3/06/1973

Response Requested to 1993 Patent Examiner's Action Survey

As part of the continuing quality reinforcement efforts of the Patent and Trademark Office, the Office has sent out a Patent Action Survey Form with each Patent Examiner's Office action mailed during a period of several weeks during December, 1993-January, 1994. **If you have received one or more of these forms, please complete each one, no later than the time of response to the Office action being surveyed.**

The survey is intended to determine whether Office actions are perceived to be clear and complete on certain specific and important items related to patent examining practices and procedures. The results of the survey will be used in the development of Office training programs. The survey is a follow-up to the Patent Action Surveys conducted in 1991 and 1992. Where training is provided to address identified deficiencies in performance, follow-up surveys are intended to be conducted in the future to determine whether the training was effective enough to improve performance in the measured areas.

The Survey Form is brief and easy to complete and does not permit identification of the respondent or of the particular application involved. The Survey Form may be completed at the time of response to the Office Action. It is possible that a practitioner may receive many Office Actions containing a Survey Form during the survey period. To have results that are meaningful, the Office needs a high response rate. Therefore, it is **important** that patent practitioners complete each survey form **no later than the time of response to the Office action being surveyed**. To assure that this form is completed and mailed back to the address indicated on the Survey Form, it would be desirable for patent practitioners to have their office managers/docketing personnel take appropriate steps to keep the form and Office action together for the practitioner's benefit.

Your cooperation in completing the Survey Form is appreciated.

Nov. 16, 1993

STEPHEN G. KUNIN
*Acting Assistant Commissioner
for Patents*

GUIDELINES FOR INTERIM EXTENSION UNDER 35 U.S.C. § 156(d)(5) OF A PATENT TERM PRIOR TO REGULATORY APPROVAL OF A PRODUCT FOR COMMERCIAL MARKETING OR USE - PUBLIC LAW 103-179 (December 3, 1993)

This notice is intended to establish initial guidelines for patent owners who are seeking interim extensions of patent terms pursuant to newly enacted 35 U.S.C. § 156(d)(5). These guidelines will be in effect until further notice. These guidelines do not affect the rights of a patent owner or the procedures to request interim extensions under 35 U.S.C. § 156(e)(2).

Section 156(d)(5)(A) of Title 35, United States Code, provides that a patent owner seeking an interim extension of the terms of a patent pursuant to its provisions must submit an application to the Commissioner of Patents and Trademarks (Commissioner) within a certain defined period of time. Section 156(d)(5) specifies certain components the application is to contain, including "such patent or other information as the Commissioner may require." See 35 U.S.C. § 156(d)(5)(A)(v). Section 156(h) pro-

vides that the "Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section." The purpose of this notice is to provide guidelines which a patent owner or its agent should use in (1) deciding whether the requirements for the submission of an application for an interim extension of the term of a patent are satisfied, and (2) making the submission of such an application to the Patent and Trademark Office.

This notice includes guidelines as to the actual content of an application for interim extension of the term of a patent. The guidelines should be used in determining whether a patent is subject to, and meets the conditions for interim extension of its term under section 156(d)(5). The guidelines should also be used in preparing and filing an application for interim extension of the patent term. If any application for interim extension of the term of a patent is filed in accordance with 35 U.S.C. § 156(d)(5), but is not in compliance with the requirements of this notice, applicant will be notified of the deficiencies in the application and will be given a period of time within which to correct the deficiencies.

GUIDELINES

§ A. Patents eligible for interim extension of the patent term.

(a) Any patent which claims a product as defined in paragraph (b) of this section, or a method of using such a product, is eligible for an interim extension of its patent term in accordance with 35 U.S.C. § 156(d)(5).

(b) The term "product" referred to in paragraph (a) of this section means a product as defined in 35 U.S.C. 156(f).

§ B. Conditions for interim extension of patent term.

A patent may be granted an interim extension of its term if:

(a) the patent claims a product or a method of using or manufacturing a product as defined in § A of this notice;

(b) the term of the patent has been extended under 35 U.S.C. § 156(e);

(c) an application for interim extension under § 156(d) is submitted pursuant to § E of this notice;

(d) the product is currently undergoing a regulatory review as described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of 35 U.S.C. § 156(g);

(e) the product has not received permission for commercial marketing or use; or, in the case of a patent claiming a method of manufacturing a product which primarily uses recombinant DNA technology in the manufacture of the product, no permission for commercial marketing or use has been granted for a product manufactured under the process claimed in the patent; and,

(f) the application is submitted during the period beginning 6 months, ending 15 days, before the expiration of the patent term; or, in the case of a subsequent interim extension, during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

§ C. Applicant for interim extension of patent term.

Any application for interim extension of a patent term must be submitted by the owner of record of the patent or its agent and must comply with the requirements of § E of this notice.

§ D. Filing date of application for interim extension of patent term.

(a) The filing date of an application for interim extension of patent term is the date on which a complete application is received in the Patent and Trademark Office, or filed pursuant to the "Certificate of Mailing" provisions of 37 CFR § 1.8 or "Express Mail" provisions of 37 CFR § 1.10.

A complete application shall include:

(1) identification of the product then under regulatory review;

(2) identification of each Federal statute under which regulatory review is occurring;

(3) identification of the patent for which an interim extension is sought;

(4) identification of each claim of the patent which claims the product or a method of using or manufacturing the product then under regulatory review;

(5) sufficient information to enable the Commissioner to determine that, except for permission to market or use the product commercially, the patent would be eligible for an extension of its term under 35 U.S.C. § 156; and,

(6) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the product or a method of using or manufacturing the product then under regulatory review and the significant dates applicable to such activities.

(b) If any application submitted pursuant to this section is held to be incomplete, applicant may seek to have this holding reviewed under 37 CFR § 1.181.

§ E. Application for interim extension of patent term.

(a) An application for interim extension of a patent term must be made in writing to the Commissioner of Patents and Trademarks.

(b) A formal application for interim extension of the patent term shall include:

(1) a complete identification of the product under regulatory review as by appropriate chemical and generic name, physical structure or characteristics, and, where the requested extension is based on a method claim, the method of using or method of manufacturing the product then under regulatory review;

(2) a complete identification of the Federal statute including the applicable provision of law under which the regulatory review is occurring;

(3) in the case of a human drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients) the use for which it was approved, and the provision of law under which it was approved;

(4) a statement that the application is being submitted within the period permitted for submission pursuant to § B of this notice, and an identification of the date of the first and last days on which the application could be submitted;

(5) a complete identification of the patent for which an interim extension is sought by the name of the inventor, the patent number, the date of issue, and the date of expiration;

(6) a copy of the patent for which an interim extension is sought, including the entire specification (with claims) and drawings;

(7) a copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent;

(8) a statement that the patent claims the product or a method of using or manufacturing the product under regulatory review,

and a showing which lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the product or a method of using or manufacturing the product under regulatory review;

(9) a statement beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. § 156(g) of the applicable current regulatory review period as follows:

(i) for a patent that claims a human drug, antibiotic, or human biological product, the effective date of the investigational new drug (IND) application and the IND number, and the date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number;

(ii) for a patent claiming a new animal drug, the date a major health or environmental effects test on the drug was initiated and any available substantiation of the date or the date of an exemption under subsection (j) of section 512 of the Federal Food, Drug and Cosmetic Act became effective for such animal drug; and the date on which a new animal drug application (NADA) was initially submitted and the NADA number;

(iii) for a patent claiming a veterinary biological product; the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective; and the date an application for license was submitted under the Virus-Serum-Toxin Act;

(iv) for a patent claiming a food or color additive, the date a major health or environment effects test on the additive was initiated and any available substantiation of that date; and the date on which a petition for product approval under the Federal Food, Drug and Cosmetic Act was initially submitted and the petition number;

(v) for a patent claiming a medical device, the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; and the date on which any application for product approval or notice of completion of a product development protocol under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application;

(10) a brief description beginning on a new page of the significant activities undertaken by the applicant during the applicable regulatory review period with respect to the product under regulatory review and the significant dates applicable to such activities;

(11) a statement that applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks any information which is material to the determination of entitlement to the interim extension sought;

(12) the prescribed fee for receiving and acting upon the application for extension (see § F of this notice);

(13) the name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for interim patent term extension are to be directed;

(14) a duplicate of the application papers, certified as such; and,

(15) an oath or declaration as set forth in paragraph (c) of this section.

(c) Any oath or declaration submitted in compliance with paragraph (b) of this section must be signed by the owner of record of the patent or its agent, specifically identify the papers and the patent for which an interim extension is sought and aver that the person signing the oath or declaration;

(1) is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters;

(2) has reviewed and understands the contents of the application being submitted pursuant to this section;

(3) believes the patent is eligible for extension pursuant to § A of this notice;

(4) believes an interim extension is justified under 35 U.S.C. § 156(d)(5) and the guidelines of this notice; and,

(5) believes the patent for which the extension is being sought meets the conditions for interim extension of the term of a patent as set forth in § B on this notice.

(d) If any application for interim extension of patent term submitted pursuant to this section is held to be informal, applicant may seek to have that holding reviewed by filing a petition with the required fee, as necessary, pursuant to 37 C.F.R. §§ 1.181, 1.182 or 1.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 C.F.R. § 1.136.

§ F. Fees for receiving and acting on application filed pursuant to 35 U.S.C. § 156(d)(5).

Pursuant to 35 U.S.C. § 156(h), the Commissioner has determined that the following fees are appropriate to cover the costs to the Patent and Trademark Office of receiving and acting upon applications for interim patent terms extension filed pursuant to 35 U.S.C. § 156(d)(5):

(a) for an initial application for "interim extension" under 35 U.S.C. § 156(d)(5)(A): \$400.00; and,

(b) for each application requesting a "subsequent interim extension" under 35 U.S.C. § 156(d)(5)(C): \$200.00.

The appropriate fee should accompany the application when filed. If a fee in a different amount is adopted in Title 37 of the Code of Federal Regulations, applicant will be refunded any excess or required to submit any deficiency.

§ G. Address for filing applications pursuant to 35 U.S.C. § 156(d)(5).

All applications for interim extension of the term of a patent and any communications relating thereto should be addressed to the Commissioner of Patents and Trademarks, Box Patent Ext., Washington, D.C., 20231. When appropriate, the communication should be marked to the attention of a particular individual.

§ H. Termination of Interim Extension.

Any interim extension granted under 35 U.S.C. § 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files additional information required under 35 U.S.C. § 156(d)(1) not contained in the application for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. § 156.

§ I. For further information contact:

Charles E. Van Horn by telephone at (703) 305-9054 or Gerald A. Dost by telephone at (703) 305-8813; or by mail marked to their attention and addressed to the Commissioner of Patents and Trademarks, Washington, D.C., 20231.

Summary

The initial guidelines set forth above are considered to be appropriate and authorized by 35 U.S.C. § 156. They will

provide appropriate guidelines to patent owners and their agents pending appropriate changes which will be made in Title 37 of the Code of Federal Regulations.

Jan. 6, 1994

BRUCE A. LEHMAN
*Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks*

DEPARTMENT OF COMMERCE

Patent and Trademark Office

**Effect of December 1, 1993 Amendments
to the Federal Rules of Civil Procedures on
Trademark Trial and Appeal Board
Inter Partes Proceedings.**

Trademark Rule 2.116(a) provides that, except as otherwise provided, and wherever applicable and appropriate, procedure and practice in Trademark Trial and Appeal Board (Board) inter partes proceedings shall be governed by the Federal Rules of Civil Procedures. Trademark Rule 2.120(a) provides, in part, that the provisions of the Federal Rules of Civil Procedure relating to discovery shall apply in opposition, cancellation, interference, and concurrent use registration proceedings except as otherwise provided in Trademark Rule 2.120; and that the opening of discovery is governed by the Federal Rules of Civil Procedure. Thus, where the Board has its own rule concerning a particular matter of practice or procedure, that rule governs; if there is no Board rule concerning the matter, the Federal Rules of Civil Procedure apply, where applicable and appropriate.

On December 1, 1993, certain of the rules in the Federal Rules of Civil Procedures were amended, and one new rule was added. Specifically, Rules 1, 4, 5, 11, 12, 15, 16, 26, 28, 29, 30, 31, 32, 33, 34, 36, 37, 38, 50, 52, 53, 54, 58, 71A, 72, 73, 74, 75, and 76 were amended, and new Rule 4.1 was added. Included in the amendments are changes in the discovery rules to require that the parties to a civil action: (1) make a series of automatic disclosures, during the pretrial stages of the proceedings, of certain evidence; (2) file the disclosures with the court; (3) meet, early in the proceeding, to discuss, inter alia, the automatic disclosure and to develop a plan for discovery; and, (4) transmit to the court a written report outlining the discovery plan. The timing of some of these matters is tied to the timing of a scheduling conference to be held, or a scheduling order to be issued, by the court. The timing and sequence of other of the matters depends upon the direction of the court. Further, parties are prohibited from seeking any of the traditional forms of discovery until after they have met and developed their discovery plan.

The Patent and Trademark Office (Office) believes that the application of the cited provisions in inter partes proceedings before the Board would increase the complexity and cost of the proceedings and would be unduly burdensome both to the Board and the parties. For these reasons, the Office is now of the opinion that these provisions would have a detrimental effect on, and are not appropriate for, Board proceedings. Moreover, the Office's Public Advisory Committee for Trademark Affairs has recommended that incorporation of the amendments in Board practice be deferred until the Office can evaluate the effects of the amendments on civil actions. On the other hand, some of the provisions added by the amendments are not objectionable, and others so clearly do not apply in, and/or are not appropriate for, Board proceedings that they need not be mentioned.

Accordingly, application of Rule 2.120(a) is hereby waived, in pertinent part, to the extent that the following provisions of the Federal Rules of Civil Procedure, as amended, which otherwise arguably would apply in Board proceedings, and which would, in the opinion of the Office, have a detrimental effect on those proceedings, shall not be applied therein unless and until further notice is given:

1. Rule 16(b) [requirement that court issue a scheduling order, after consulting with parties by scheduling conference, telephone, mail, or other suitable means]

2. Rules 26(a)(1)-26(a)(4) [requirements for series of automatic disclosures of evidence]